PMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0317] (formerly Docket No. 03D–0317)

Guidance for Review Staff and Industry on Good Review Management Principles and Practices for Prescription Drug User Fee Act Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for review staff and industry entitled "Good Review Management Principles and Practices for PDUFA Products." This is one in a series of guidance documents that FDA agreed to draft and implement in conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Food and Drug Administration, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of

2003D-0317

NAD 2

Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The guidance may also be obtained from CBER by mail by calling 1–800–835–4709, or 301–827–1800. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John Jenkins, Center for Drug Evaluation and Research (HFD–020), Food and Drug Administration, suite 7215, 5515 Security Lane, Rockville, MD 20852, 301–594–3937; or Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for review staff and industry entitled "Good Review Management Principles and Practices for PDUFA Products." In conjunction with the June 2002 reauthorization of PDUFA, FDA agreed to meet specific performance goals (PDUFA Goals). The PDUFA Goals include providing guidance to industry and review staff in CDER and CBER on the good review management principles and practices (GRMPs) for the conduct of the first cycle review of a new drug application (NDA), a biologics license application (BLA), or an efficacy supplement under PDUFA.

The GRMPs in this guidance are based on the collective experience of CDER and CBER with review of applications for PDUFA products and are intended to promote efficient and consistent management of application reviews. The GRMPs also clarify roles and responsibilities of review staff in managing the review process and identify ways in which NDA and BLA applicants may further the effectiveness and efficiency of the review process.

In the **Federal Register** of July 28, 2003 (68 FR 44345), FDA published a notice announcing the availability of a draft version of this guidance. FDA received a number of comments when it issued the draft version of this guidance. We have considered the comments on the draft guidance carefully and have made some changes to address those comments. The guidance has been revised to clarify the principles on which our current and developing practices are based. We have also added general internal timelines for important milestones associated with the review process.

The GRMPs also include the agency's current best practices, as well as goals for review management improvements. The GRMPs are an important foundational component of FDA's program to more fully implement a quality systems approach for the new drug and biologics review and approval process.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on GRMPs for PDUFA products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm,* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: 3/25/05
March 25, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

BILLING CODE 4160–01–S